CLAIMS

What is claimed is:

1. A pharmaceutical dosage form suitable for oral administration comprising a molded microcellular polymeric material and a pharmaceutically acceptable active agent.

2. The pharmaceutical dosage form according to claim 1 wherein the molded microcellular polymeric material is a non-thermosetting polymerized plastics material.

3. The pharmaceutical dosage form according to claim 2 wherein the non-thermosetting polymerized plastics material contains at least one polyol, and at least one non-thermosetting modifier, and/or a non-thermosetting polymer.

4. The pharmaceutical dosage form according to claim 3 wherein the non-thermosetting polymerized plastics material contains at least one polyol, and at least one non-thermosetting modifier.

5. The pharmaceutical dosage form according to claim 3 wherein the polyol is lactitol, xylitol, sorbitol, maltitol, or mannitol, or combinations thereof.

6. The pharmaceutical dosage form according to claim 3 wherein the non-thermosetting modifier is a starch, maltodextrin, a dextrose equivalent, polyalditol a hydrogenated starch hydrosylate, or a mixture thereof.

7. The pharmaceutical dosage form according to claim 6 wherein the starch is pregelatinized corn starch, corn starch, potato starch, rice starch, hydroxyethyl starch, wheat starch, tapioca starch, or waxy maize starch, or mixtures thereof.

8. The pharmaceutical dosage form according to claim 6 wherein the non-thermosetting modifier is a maltodextrin.

9. The pharmaceutical dosage form according to claim 3 wherein the non-thermosetting polymer is carboxymethyl cellulose sodium, methyl cellulose, ethylcellulose, hydroxyethylcellulose (HEC), hydroxypropylmethyl cellulose (HPMC), hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, noncrystalline cellulose, starch and its derivatives, and sodium starch glycolate or mixtures thereof.

10. The pharmaceutical dosage form according to any one of claims 1 to 9 which optionally further comprises a sweetener, a disintegrant, a binder, a lubricant, or an opacifier.

11. The pharmaceutical dosage form according to claim 10 wherein the disintegrant is croscarmellose sodium, sodium starch glycolate, sodium carboxymethyl-cellulose, Ac-di-sol®, carboxymethyl-cellulose, veegum, an alginate, agar, guar, tragacanth, locust bean, karaya, pectin, or crospovidone.

12. The pharmaceutical dosage form according to claim 10 wherein the lubricant is glycerol monosterate, stearyl alcohol NF, stearic acid NF, Cab-O-Sil, Syloid, zinc stearate USP, magnesium stearate NF, calcium stearate NF, sodium stearate, cetostrearyl alcohol NF, sodium stearyl fumerate NF, or talc.

13. The pharmaceutical dosage form according to claim 10 wherein the opacifiers is talc USP, calcium carbonate USP, or kaolin USP.

14. The pharmaceutical dosage form according to claim 1 wherein the pharmaceutically acceptable active agent is selected from an analgesic, an anti-inflammatory agent, an anthelmintic, anti-arrhythmic, antibiotic, anticoagulant, antidepressant, antidiabetic, antiepileptic, antihistamine, antihypertensive, antimuscarinic, antimycobacterial, antineoplastic, immunosuppressant, antithyroid, antiviral, anxiolytic and sedatives, beta-adrenoceptor blocking agents, cardiac inotropic agent, corticosteroid, cough suppressant, diuretic, dopaminergic, immunological agent, lipid regulating agent, muscle relaxant, parasympathomimetic, parathyroid, calcitonin and biphosphonates, prostaglandin, radiopharmaceutical, anti-allergic agent, sympathomimetic, thyroid agent, PDE IV inhibitor, CSBP/RK/p38 inhibitor, and a vasodilator.

15. The pharmaceutical dosage form according to claim 1 wherein the molded microcellular polymeric material is a thermoplastic polymer.

16. The pharmaceutical dosage form according to claim 15 wherein the thermoplastic polymer is polyethylene oxide, hydroxypropylcellulose, polyethylene glycol, polyvinyl pyrrolidone, copovidone, or povidone or mixtures thereof.

17. The pharmaceutical dosage form according to claim 16 wherein the polymer is polyethylene oxide, hydroxypropylcellulose, or a mixture thereof.

18. The pharmaceutical dosage form according to claim 15 which further comprises a non-thermosetting polymerized plastics material.

19. The pharmaceutical dosage form according to claim 18 wherein the non-thermosetting polymerized plastics material contains at least one polyol, and at least one non-thermosetting modifier, and/or a non-thermosetting polymer.

20. The pharmaceutical dosage form according to any one of claims 1 to 8, or 10 to 19 wherein the microcellular polymeric material is a closed cell foam.

21. A pharmaceutical dosage form comprising: a rigid microcellular foam consisting of a solid excipient having voids of substantially uniform size with a maximum void dimension in the range from about 2 to 100 microns and a void fraction in the range of about 5 to 95 percent, the solid excipient comprising a non-thermosetting polymerized plastic material and an active

pharmaceutical agent combined in a homogeneous solid mixture.

22. The pharmaceutical dosage form according to claim 21 wherein the non-thermosetting polymerized plastics material contains at least one polyol, and at least one non-thermosetting modifier, or non-thermosetting polymer.

23. The pharmaceutical dosage form according to claim 21 wherein the polyol is lactitol, xylitol, sorbitol, maltitol, or mannitol, or combinations thereof.

24. The pharmaceutical dosage form according to claim 21 wherein the non-thermosetting modifier is a starch, maltodextrin, a dextrose equivalent, polyalditol a hydrogenated starch hydrosylate, or a mixture thereof.

25. The pharmaceutical dosage form according to claim 24 wherein the starch is pregelatinized Corn Starch, Corn Starch, Potato starch, Rice starch, hydroxyethyl starch, Wheat starch, Tapioca starch, or Waxy maize starch.

26. The pharmaceutical dosage form according to claim 22 wherein the nonthermosetting modifier is a maltodextrin.

27. The pharmaceutical dosage form according to claim 21 wherein the non-thermosetting polymer is carboxymethyl cellulose sodium, methyl cellulose,

ethylcellulose, hydroxyethylcellulose (HEC), hydroxypropylmethyl cellulose (HPMC), hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, noncrystalline cellulose, starch and its derivatives, and sodium starch glycolate or mixtures thereof.

28. The pharmaceutical dosage form according to any one of claims 21 to 27 which optionally further comprises a sweetener, a disintegrant, a binder, a lubricant, or an opacifier.

29. The pharmaceutical dosage form according to claim 28 wherein the disintegrant is croscarmellose sodium, sodium starch glycolate, sodium carboxymethyl-cellulose, Ac-di-sol®, carboxymethyl-cellulose, veegum, an alginate, agar, guar, tragacanth, locust bean, karaya, pectin, or crospovidone.

30. The pharmaceutical dosage form according to claim 28 wherein the lubricant is glycerol monosterate, stearyl alcohol NF, stearic acid NF, Cab-O-Sil, Syloid, zinc stearate USP, magnesium stearate NF, calcium stearate NF, sodium stearate, cetostrearyl alcohol NF, sodium stearyl fumerate NF, or talc.

31. The pharmaceutical dosage form according to claim 28 wherein the opacifiers is talc USP, calcium carbonate USP, or kaolin USP.

32. The pharmaceutical dosage form according to claim 21 wherein the active pharmaceutical agent is

selected from an analgesic, an anti-inflammatory agent, an anthelmintic, anti-arrhythmic, antibiotic, anticoagulant, antidepressant, antidiabetic, antiepileptic, antihistamine, antihypertensive, antimuscarinic, antimycobacterial, antineoplastic, immunosuppressant, antithyroid, antiviral, anxiolytic and sedatives, beta-adrenoceptor blocking agents, cardiac inotropic agent, corticosteroid, cough suppressant, diuretic, dopaminergic, immunological agent, lipid regulating agent, muscle relaxant, parasympathomimetic, parathyroid, calcitonin and biphosphonates, prostaglandin, radiopharmaceutical, anti-allergic agent, sympathomimetic, thyroid agent, PDE IV inhibitor, CSBP/RK/p38 inhibitor, and a vasodilator.

33. The pharmaceutical dosage form according to claim 21 wherein the solid excipient further comprises a thermoplastic polymer.

34. The pharmaceutical dosage form according to claim 33 wherein the thermoplastic polymer is polyethylene oxide, hydroxypropylcellulose, polyethylene glycol, polyvinyl pyrrolidone, copovidone, or povidone or mixtures thereof.

35. The pharmaceutical dosage form according to claim 34 wherein the polymer is polyethylene oxide, hydroxypropylcellulose, or a mixture thereof.

36. The pharmaceutical dosage form according to claim 21 wherein the non-thermosetting polymerized plastics material contains at least one polyol, and at

least one non-thermosetting modifier, and optionally a or a thermosetting polymer.

37. The pharmaceutical dosage form according to any one of claims 21 to 27, and 29 to 36 wherein the microcellular polymeric material is a closed cell foam.

38. A pharmaceutical dosage form according to claim 21, in which the homogeneous solid mixture has a sufficiently high solubility in saliva that the dosage form dissolves substantially immediately in the mouth upon oral administration.

39. A pharmaceutical dosage form according to claim 21, in which the voids are in the form of closed cells.

40. A pharmaceutical dosage form according to claim 21, in which the rigid microcellular foam is enclosed within a skin having a density substantially greater than that of the microcellular foam, but having the same composition as that of said solid mixture.

41. A pharmaceutical dosage form according to claim 21, in which the overall density of the dosage form is substantially less than that of stomach fluids, whereby the dosage form is gastro-retentive.

42. A method for making pharmaceutically acceptable dosage forms including a pharmaceutical agent and a non-thermosetting excipient polymer, the method comprising the steps of:

heating the non-thermosetting excipient polymer to a temperature at which the polymer can be molded;

applying pressure to the polymer to maintain the polymer at elevated pressure;

while maintaining the polymer at elevated pressure, forming a single phase solution comprising said polymer and a substance which is substantially non-reactive with said pharmaceutical agent to form a single-phase solution, said substance being a gas under ambient temperature and pressure;

forming the polymer into solid dosage forms by injection molding; and

at a time prior to the forming of the polymer into solid dosage forms, mixing said pharmaceutical agent with the polymer to form a homogeneous mixture;

wherein, in the process of forming the polymer into solid dosage forms, the elevated pressure is reduced to a level at which a very large number of cells is nucleated, each cell containing said gas; and

after the cells are nucleated, the temperature of the polymer is rapidly reduced to limit cell growth.

43. The method according to claim 42, in which the step of mixing said pharmaceutical agent with the polymer to form a homogeneous mixture is carried out prior to the steps of heating and applying pressure.

44. The method according to claim 42, in which said single phase solution is formed by introducing said substance into said polymer by injecting said substance under pressure.

45. The method according to claim 42, in which said substance is introduced into the polymer in the form of a gas.

46. The method according to claim 42, in which said substance is introduced into the polymer in the form of a gas, and the gas introduced into the polymer remains in solution in the polymer while the polymer is under a pressure greater than ambient pressure.

47. The method according to claim 42, in which said substance is introduced into the polymer in the form of a gas, the amount of gas introduced into the polymer is sufficient to form a saturated single phase solution, and the level to which the elevated pressure is reduced is a level at which the single phase solution becomes thermodynamically unstable and gas evolves from the solution in the form of bubbles.

48. The method according to claim 42, in which said substance is introduced into the polymer in the form of a supercritical fluid.

49. The method according to claim 42, in which the pressure and temperature reduction steps are carried out at rates such that the maximum void dimension in the solid dosage form is in the range from about 2 to 100

microns and the void fraction is in the range of about 5 to 95 percent.

50. The method according to claim 42, in which the polymer is formed into pellets by melt extrusion prior to the injection molding step.